

# Johnson & Johnson

New Brunswick, N.J.

**Subject:** An Estimated Upper Limit for Talc Dust  
Exposure of Infants Compared with the  
OSHA Threshold Limit Value for Talc Miners

February 19, 1974

Dr. W. Nashed:

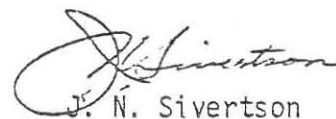
Upper limits for talc dust exposure for infants in a one week period were estimated on a particle-time basis from experimental data supplied by Dr. F. D. Pooley and Alvin N. Eden, M.D. The experimental values used to estimate an upper limit for talc exposure for infants were those which correspond to maximum exposure conditions. Whenever estimates were employed, conservative numbers were selected, that is, values which tended to increase the estimated exposure.

A second estimate was made which more closely approximates median exposure levels of infants to talc dust, but even this was based on conservative assumptions and probably represent an exposure level which is generally greater than normal. For example, all estimates were based on applying the talc directly to the diaper area from a container, which is the mode of application which creates the greatest concentration of talc dust. An alternate mode which produces substantially less dust is employed by many mothers who transfer talc from the container to their hand and gently stroke this powder onto the infant.

To provide a basis of comparison a particle-time exposure was computed for a talc miner in contact with the OSHA T.L.V. for talc of 20 mppcf for a 40 hour week.

This particle-time exposure value for a miner is at least 370 times the corresponding upper limit exposure value for an infant and is about 7840 times the exposure of an infant under more nearly median conditions.

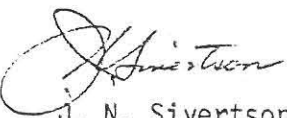
For ease of comparing results the exposure levels are presented in the attached table. A complete summary of the computations and assumptions are discussed in the attached report.

  
J. N. Sivertson

clc

Summary Table Comparing the Talc Dust Exposure Levels  
for Talc Miners and Infants

<u>Type of Estimate</u>	<u>Exposure Levels</u> <u>mppcf-hrs per week</u>	<u>Ratio of Miner</u> <u>to Infant Exposure</u>
OSHA T.L.V. for Miners	800	---
Infant - Upper Limit Exposure	2.16	370
Infant - Median Exposure	0.102	7,840

  
J. N. Sivertson  
Manager  
Statistical and  
Computer Operations

clc

February 19, 1974

COMPARISON OF TALC DUST EXPOSURE

FOR

INFANTS AND TALC MINERS

J. N. Sivertson  
Statistical & Computer  
Operations  
February 19, 1974

## TABLE OF CONTENTS

<u>Section</u>	<u>Subject</u>
I.	Comparison of Talc Dust Exposure for Infants and Talc Miners.
II.	Report by F. D. Pooley on Dusting Experiments Performed with JOHNSON's* Brand Baby Powder.
III.	Data Submitted by Alvin N. Eden, M.D. Investigating Methods by Which Baby Powder was Applied to Infants by Their Mothers.
IV.	Data Submitted by Alvin N. Eden, M.D. Investigating Time (In Seconds) Required for the Application of Baby Powder to Different Areas of Infants by Various Methods of Application and Weights of Powder Per Application.
V.	Summary of <u>Parameters Associated with Powdering a Baby as They Affect the Talc Cloud</u> Submitted by Dr. F. D. Pooley.

\* Trademark of JOHNSON & JOHNSON.

COMPARISON OF TALC DUST EXPOSURE  
FOR INFANTS AND TALC MINERS

Introduction:

In this report the exposure of infants to talc dust has been estimated from experimental work conducted by Doctors Pooley and Eden. This exposure is expressed in units of concentration-hours, that is, the product of the concentration in air and the number of hours in contact with this air. In this instance the concentration is expressed as million particles per cubic foot (mppcf) of air; thus, exposure is expressed in terms of mppcf-hours (or in some instances, mppcf-minutes). It is possible to express the OSHA Threshold Limit Value (T.L.V.) for talc miners on a similar basis in order to compare exposures.

The experimental results in the attached reports by Doctors Pooley and Eden exhibit considerable variability, and to illustrate the effect of this variability two different exposure estimates will be developed. The first estimate will be an upper limit for the exposure of infants to talc dust, and the second will establish an exposure level closer to median conditions.

On occasion it will be necessary to make certain assumptions if experimental data are either missing or incomplete. It will be clear from the discussions in the text that assumptions made affecting infant exposure are purposely made conservative (i.e. tend to make the exposure level high). Thus, all the results including the median exposure results for infants are probably greater than normal.

Estimation of an Upper Limit for Infant Exposure to Talc Dust:

The data on which all computations in this report are based may be found in the following four reports:

1. Report of Dusting Experiments Performed with Johnson & Johnson Baby Powder by Dr. F. D. Pooley of University College, Cardiff, February 10, 1972.
2. A clinical study conducted by Alvin N. Eden, M.D. to determine the methods by which baby powder was applied to infants by their mothers and the daily frequencies of application, submitted November 22, 1971.
3. A second clinical study conducted by Alvin N. Eden, M.D. to determine the number of seconds required for the application of baby powder to different areas of the infants and the weight of powder employed.
4. A summary of Parameters Associated with a Baby as They Affect the Talc Cloud by Dr. F. D. Pooley.

In report 1 above, Doctor Pooley simulated the application of talcum powder to the diaper area of an infant in a series of seven trials. In order to obtain sufficiently large dust clouds to sample effectively with a Mining Research Establishment (M.R.E.) sampler, he emptied a 9 ounce (255 grams) container of Johnson's Brand Baby Powder by shaking and squeezing in each of seven experiments. The length of time taken to empty each container ranged from 6.0 to 9.8 minutes (estimated by dividing the total

air volume collected in each experiment by the sampling rate of 2.5 liters per minute). The air was sampled from a position in space approximating the location of an infant's nose relative to the dusting area. In this series of tests he collected a total volume of 137.0 liters of air (total time =  $137.0/2.5 = 54.8$  minutes) while dusting a total of 1785 grams (=  $7 \times 255$ ) of powder. This corresponds to an average dusting rate of  $1785/58.4 = 32.6$  grams per minute or  $32.6/60 = 0.523$  grams per second. In contrast Doctor Eden found (Report 3 above) that the maximum dusting rate was 0.147 grams per second and the median rate, 0.060 grams per second. Thus, Doctor Pooley created dust  $0.523/.147 = 3.56$  times faster than the maximum observed by Doctor Eden in actual use tests and  $0.523/.060 = 8.72$  times faster than the median rate.

Since Doctor Pooley found 2.12 mppcf of talc dust in air at an accelerated dusting rate, an estimate of the talc dust concentration under median application rates is obtained by proportioning concentration to rate as follows:

$$\frac{2.12}{0.060} \div \frac{0.523}{0.523} = 0.243 \text{ mppcf}$$

Note:  $(.060/.523) \times 100 = 11.5$  percent.

Report 2 contained data regarding the frequency of talc application and application times and Report 3 also contained data about application times. A daily frequency distribution was prepared from data in

Report 2. This distribution was based on applying powder directly from the canister to the diaper area, since this mode of use represents the type of application employed by 67 percent of the mothers and is the dustiest mode of application. Although data on the duration of talc applications in the two reports were similar, data from Report 3 was used to prepare a distribution of application times since the data recorded in the hospital was more precise. Only data pertaining to timing the direct application of talc to the diaper site was employed.

The two frequency distributions employed are as follows:

From Report 2		From Report 3	
Frequency of Use		Application Times	
Weighting Factor*	Daily Frequency of Use	Weighting Factor*	Time in Seconds
6	1	3	3
22	2	3	4
5	3	19	10m
6	4	11	15
8	5m	1	18
18	6	4	20
6	7	2	25
6	8		
1	9		
		Total: 43	
Total: 78			

m = median value

\* Weighting factors are the number of times the data were reported in the study. In the table on the left the factors shown represent the original weighting factors multiplied by two to eliminate fractions.



After talc has been applied the major portion of the dust cloud settles very rapidly as shown by Doctor Pooley (See Report 4 above and Figure I). He found, for example, that about 2.1 percent of the talc particles remained in suspension 1.25 minutes after the beginning of a 10 second (= 0.17 minute) dusting experiment (See Table I). The data in the first two columns of Table I were transcribed from Doctor Pooley's summary dealing with 10 second dusting in the "room" (Report 4) or were estimated from his data. Estimates are indicated by asterisks. The "room" data were used, since the room under discussion was the same room Doctor Pooley employed to determine the dust concentrations in his talc dusting experiments (Report 1).

The data in the Column 3 of Table I represent the percentage of particles remaining in the air at the end of the times shown in column 1, and are computed from the data in column 2. These number percentages were then used to compute the talc dust concentrations shown in column 4. The numbers in column 4 are percentages of the 2.12 mppcf of air as determined by Doctor Pooley's talc dusting simulations (Report 1). Column 5 in Table 1 is the average concentration of talc dust during the time intervals indicated by the brackets.

Using the above data and the curve shown in Figure I an estimation of an upper limit for talc dust exposure of an infant may be made by employing the following additional information and assumptions:

1. The maximum time required for applying talc directly to an infant's body was reported by Doctor Eden (Report 3) as 25 seconds (0.42 minutes).
2. The maximum daily frequency for talc application to an infant was reported by Doctor Eden (Report 2) as 9 times.
3. Two different conditions and their associated time intervals are related to the exposure of infants to talc dust.

<u>Condition</u>	<u>Duration (Mins.)</u>
3.1 Direct application of talc	0.42
3.2 Period for dust settling	1.08

The 1.08 minutes is the difference between 1.25 minutes elapsed time from the start of dusting and the 0.17 minutes (10 seconds) of dusting described in Report 4 ( $1.25 - .17 = 1.08$ ).

Table for Estimating an Upper Limit  
For Infant Exposure to Talc Dust

<u>Condition</u>	<u>Duration</u> <u>Minutes</u>	<u>Talc Concentration</u> <u>mppcf*</u>	<u>Exposure</u> <u>mppcf-minutes</u>
1. Applying Talc	0.42	2.12	0.890
2. Dust Settles	1.08	1.08	1.166
Exposure per application:			2.056

Upper Limit for daily exposure  $9 \times 2.056 = 18.50$  mppcf-Minutes

Upper Limit for Weekly Exposure

$18.50 \times 7/60 = 2.16$  mppcf-Hours

\*From Column 5 in Table I.

Weekly Talc Dust Exposure of a Miner Working in Dust Concentrations  
Corresponding to the OSHA Threshold Limit Value

In order to estimate a weekly exposure of a talc miner on an equivalent basis for purposes of comparison, the OSHA Threshold limit value (T.L.V.) of 20 mppcf is employed (Reference b). The total weekly equivalent of the T.L.V. exposure would be  $20 \times 40 = 800$  mppcf-Hrs. and this number is 370 times greater than the upper limit for infant exposure.

It is worth noting that the factor of 370 does not take into consideration the differences in minute volumes (liters of air inhaled per minute) between an infant and a miner. According to reference (a) the maximum minute volume for an infant is 0.697 li. per minute, while for an adult male doing light work the average value is 28.6 li. per minute and, at rest, is 7.43. As a conservative estimate consider the miner to be doing light work 1/4 of the time; then his expected minute volume would be  $.25(28.6) + .75(7.43) = 12.72$  li per minute. Thus, the miner would, on the average, breathe  $12.72/.697 = 18.25$  times more air than the infant.

Estimation of An Exposure Level of Infants to Talc Dust  
Which is Closer to Median Conditions

To estimate an exposure closer to median conditions the factors to be considered are:

1. The concentration of talc dust in the air during the talc application period is 0.243 mppcf as shown on page 3, and during the dust settling period, 0.124 mppcf. (11.5 percent of concentrations shown in Table I, Col. 5).

2. The median daily frequency of talc application is 5.
3. Two different conditions and their associated time intervals are related to the more nearly median exposure of infants to talc dust.

<u>Condition</u>	<u>Duration (Mins.)</u>
3.1 Direct application of talc	0.17
3.2 Period for dust settling	1.08

Table for Estimating Closer to the Median Exposure  
of Infants to Talc Dust

<u>Condition</u>	<u>Duration Minutes</u>	<u>Talc Concentration mppcf*</u>	<u>Exposure mppcf-Minutes</u>
1. Applying Talc	0.17	0.243	0.0413
2. Dust Settles	1.08	0.124	<u>0.1339</u>

Exposure per application: 0.1752

Median daily exposure  $5 \times 0.1752 = 0.876$  mppcf-minutes

Estimated Median Weekly Exposure

$$0.876 \times 7/60 = 0.102 \text{ mppcf-Hrs.}$$

\* From Column 6 in Table I.

Ratio of equivalent T.L.V. for a miner to the above total weekly exposure is  $800/.102 = \underline{7840}$ .

Summary Table Comparing the Talc Dust Exposure Levels  
for Talc Miners and Infants

<u>Type of Estimate</u>	<u>Exposure Levels</u> <u>mppcf-hrs per week</u>	<u>Ratio of Miner</u> <u>to Infant Exposure</u>
OSHA T.L.V. for Miners	800	---
Infant - Upper Limit Exposure	2.16	370
Infant - Median Exposure	0.102	7,840

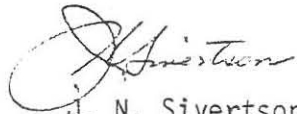
  
J. N. Sivertson  
Manager  
Statistical and  
Computer Operations

Table I

Col. 1	2	3	4	5	6
<u>Minutes After Starting Talc Application</u>	<u>Data from Pooley's Talc Dust Settling Experiment mppcf</u>	<u>Percent of Number Present at End of Dusting For 10 Secs (.17 Min.)</u>	<u>Particle Count Estimated From Pooley's Talc Application Studies mppcf</u>	<u>Estimated Count at Interval Midpoint mppcf</u>	<u>Estimated Count 11.5% of Col. 5 mppcf</u>
0.17	4.7*	100.0	2.12	2.12	.243
0.25	3.9	83.0	1.76	1.08	.124
0.50	1.72	36.6	0.78		
1.00	.24	5.1	0.11		
1.25	.1**	2.1	0.045		

\* Estimated from original data:  $3.9 - 3.1 = 0.8$   
 $0.8 + 3.9 = 4.7$

\*\* Doctor Pooley stated that no appreciable collection of particles was obtained after 75 seconds (1.25 Minutes). The concentration at 1.25 Minutes was estimated to be 0.1 mppcf.

- REFERENCES -

- (a) Biology Data Book, Federation of American Societies  
for Experimental Biology, p. 220, 1964.
- (b) "Threshold Limit Values for Chemical Substances in  
Workroom Air Adopted by ACGIH for 1973", p. 33.



FIGURE 1

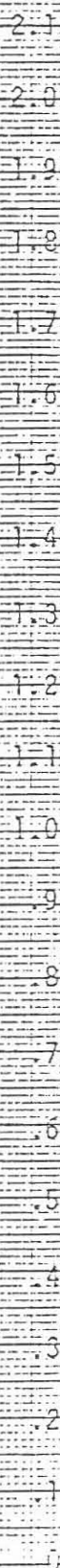
PARTICLE COUNTS IN AIR AFTER APPLYING TALC  
TO INFANTS UNDER EXTREME DUSTING CONDITIONS

MILLION PARTICLES PER CUBIC FOOT

2.2  
2.1  
2.0  
1.9  
1.8  
1.7  
1.6  
1.5  
1.4  
1.3  
1.2  
1.1  
1.0  
.9  
.8  
.7  
.6  
.5  
.4  
.3  
.2  
.1  
0

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

MINUTES





Section II

REPORT BY F. D. POOLEY ON DUSTING EXPERIMENTS

PERFORMED WITH JOHNSON'S\* BRAND BABY POWDER

\* Trademark of JOHNSON & JOHNSON